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K052550

10.0 SUMMARY OF THE SAFETY AND EFFECTIVENESS

International Medsurg Connection Surgical Gown

Manufacturer:	International Medsurg Connection, Inc. 935 N Plum Grove Road, Suite F Schaumburg, Illinois 60173-4770
Regulatory Contact:	Manny Gupta Vice President / General Manager International Medsurg Connection, Inc. 935 N Plum Grove Road, Suite F Schaumburg, Illinois 60173-4770
Telephone:	847-619-9929
Date Summary Prepared	August 5, 2005
Product Trade Name:	IMC Surgical Gowns - Multiple
Common Name:	Surgical Gown.
Classification:	Class II
Predicate:	Surgical Gowns, Reference K030364 owned by DeRoyal Industries.
Description:	Surgical Gowns including various sizes and material.

Intended Use:
International Medsurg Connection's Surgical Gown is intended to be used as Patient protective coverings used to isolate incision sites and protect against contamination during surgical procedures.

Substantial Equivalence:
The International Medsurg Connection Surgical Gowns are substantially equivalent to the Surgical Gown sold by DeRoyal Industries, Reference K030364.

IMC GOWN LIST

Catalog Number	Description
Surgical Gowns	
260-2001	Non reinforced Large
260-2002	Non reinforced X-Large
260-2003	Non reinforced XX-Large
260-2101	Fabric reinforced Large
260-2102	Fabric reinforced X-Large
260-2103	Fabric reinforced XX-Large
260-2201	Poly-reinforced Large
260-2202	Poly-reinforced X-Large
260-2203	Poly-reinforced XX-Large
260-2301	Breathable Large, Extra Long
260-2302	Breathable X-Large, Extra Long
260-2303	Breathable XX-Large, Extra Long
260-9211	Fabric reinforced Large, Extra Long
260-9212	Fabric reinforced X-Large, Extra Long
260-9115	Non reinforced Large, Extra Long
260-9116	Non reinforced X-Large, Extra Long

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They provide the following characteristics:

Intended use is the same
Similar configurations
Similar materials

Summary of testing:

All material used in the fabrication of the IMC Surgical Gowns were evaluated for:

Test	Standard
Cytotoxicity	ISO 10993 – Part 5
Skin Irritation	ISO 10993 – Part 10
Skin Sensitivity	ISO 10993 – Part 11
Systemic Toxicity	ISO 10993 – Part 11
Flammability	16 CFR Part 1610
Hydrostatic Pressure	AATCC 127
Impact Penetration	AATCC 42
Lint	IST 160.1
Tensile Strength	ASTM D5034

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2005

Mr. Manny Gupta
Vice President/General Manager
International Medsurg Connection, Incorporated
935 North Plum Glove Road, Suite F
Schaumburg, Illinois 60173-4770

Re: K052550
Trade/Device Name: IMC Surgical Gowns-Various Sizes and Configurations, Per Attached List
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: November 3, 2005
Received: November 7, 2005

Dear Mr. Gupta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

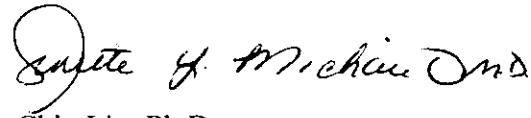
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510K Number : K052550

Device name: IMC Surgical Gowns – Various sizes and configurations per attached list

Indication For Use:

This device is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids and particulate matter.

This submission includes Surgical Gowns that will be sold both sterile and non-sterile. Non-sterile surgical gowns are to be sold to OEMs for EtO sterilization according to ISO 11135. Sterile Surgical Gowns are to be sold directly to users after EtO sterilization validation to ISO 11135.

Prescription Use__X_____ AND/OR Over-The counter Use_____
(Partb21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda A Murphy 11/17/05

(Division Sign-off)
Division of anesthesiology, General Hospital.
Infection Control Dental Devices